

## REMARKS/ARGUMENTS

### *Status of Claims*

Claims 1 and 17 have been amended.

Claims 11-13, 16, and 20-29 have been previously canceled.

Claims 2-10, and 30-32 have been previously withdrawn.

Thus, claims 1-10, 14-15, 17-19, and 30-32 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

### *Examiner Interview*

Applicants thank the Examiner for extending the courtesy of a telephonic interview on June 30, 2010 wherein the pending claims and the prior art of record were discussed. The Interview Summary mailed on July 6, 2010 accurately reflects the content of the interview.

### *Claim Rejections – 35 U.S.C. § 112*

Claims 1, 14-15, and 17-19 recite the limitation “the mixture” in independent claims 1 and 17. Applicants have amended claims as suggested by the Examiner to provide sufficient antecedent basis for the limitation “the mixture.” Applicants respectfully request withdrawal of the rejection.

### *Claim Rejections – 35 U.S.C. § 103*

Claims 1, 14-15, and 17-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schwartz, et al., U.S. Patent No. 6,500,987 (hereinafter “*Schwartz*”) in view of Am Ende, et al., U.S. Patent No. 6,517,866 (hereinafter “*Am Ende*”). Claims 14 and 15 depend from claim 1 while claims 18 and 19 depend from claim 17. Thus, the pending claims stand or fall on the application of the cited references to independent claims 1 and 17.

Applicants submit the pending claims are patentable over the prior art as the ordinarily skilled artisan would not have a reasonable expectation of success in achieving the instantly claimed subject matter. According to MPEP 2143.02 “[t]he prior art can be modified or combined to reject claims as *prima facie* obvious as **long as there is a reasonable expectation of success**. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986),” emphasis added.

Applicants’ have amended claim 1 to recite:

A process for the preparation of sertraline hydrochloride Form V **consisting essentially of:**

- a. suspending/dissolving **sertraline acetate** in suitable solvents to form a mixture;
- b. adjusting the pH of the mixture to a value of from 1 to 2 with aqueous hydrogen chloride at a temperature of 25°C;
- c. stirring the mixture at 25°C; and
- d. isolating and drying under vacuum to obtain sertraline hydrochloride Form V.

*See supra*, emphasis added. Independent claim 17 has been amended to include similar limitations. Support for these amendments can be found at least in part in paragraph [0045] of the instant application<sup>1</sup>. As per the above mentioned Examiner Interview, Applicants have amended the instant claims to remove the “comprising” language. Consequently, Applicants’ claim 1 recites the preparation of sertraline hydrochloride Form V from **sertraline acetate**. In claim 17, Applicants recite the limitation “suspending/dissolving sertraline base in acetic acid.” *See supra*. In both claims 1 and 17 of the instant application, **an acetate moiety is present in the reaction mixture** during formation of sertraline hydrochloride Form V. Applicants note that *Schwarz* exemplifies the preparation of sertraline hydrochloride Form V from **sertraline free base**. The Office Action asserts that the instantly claimed subject matter is obvious when the sertraline acetate of *Ann Ende* is substituted for the sertraline mandelate of *Schwarz* in preparation of the free base. The Office

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<sup>1</sup> All references are made to the published instant application, U.S. Patent Application No. 2007/0117781 A1.

Action further asserts that one of skill in the art would be motivated to make this substitution “because sertraline acetate is an equivalent of sertraline mandelate.” See Office Action, page 7. Applicants contend that the Office Action’s assertion that sertraline mandelate and sertraline acetate are equivalent is scientifically unsupportable. Particularly, Applicants note that when sertraline acetate is utilized in the synthesis of sertraline hydrochloride, acetic acid (being a weaker acid than mandelic acid) is more easily replaced by hydrochloric acid. Additionally, acetic acid being a lower molecular weight carboxylic acid displays a higher solubility in water when compared to the higher molecular weight mandelic acid. This is advantageously exploited in the instantly claimed subject matter as the acetic acid formed in the course of the instantly claimed process remains in liquid form and can be easily removed from the product by filtration. In contrast, mandelic acid would precipitate from solution and could not be removed from the product by filtration. An additional indication of the nonequivalence of the acetate and mandelate salts is that, while sertraline acetate may be prepared *in situ* by reaction of the sertraline free base with acetic acid in the absence of solvent, a similar process is not possible for the *in situ* preparation of sertraline mandelate in the absence of solvent. See Example 5 of the instant application.

Applicants submit that for at least the reasons set forth herein one of ordinary skill in the art **would not** find sertraline mandelate to be equivalent to sertraline acetate. Consequently, it would not be obvious to one of ordinary skill in the art to substitute sertraline acetate for sertraline mandelate as the artisan would not have a reasonable expectation of success in obtaining the instantly claimed sertraline hydrochloride Form V. In consideration of the foregoing, Applicants respectfully submit the pending claims are patentable over the cited references.

## CONCLUSION

Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections are respectfully requested by Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Office Action dated April 13, 2010 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,  
CONLEY ROSE, P.C.

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